

C64-02178

PROPOSED RESEARCH PROGRAM

on

DEVELOPMENT OF A COMBUSTIONLESS  
CIGARETTE

to

PHILIP MORRIS, INCORPORATED

February 14, 1964

BATTELLE MEMORIAL INSTITUTE

505 King Avenue  
Columbus, Ohio 43201

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# Battelle Memorial Institute

505 KING AVENUE COLUMBUS, OHIO 43201

AREA CODE 614 TELEPHONE 299-3191

February 14, 1964

Dr. Helmut Wakeham  
Director of Research  
Philip Morris, Incorporated  
McComas Research Center  
P. O. Box 3D  
Richmond 6, Virginia

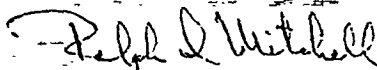
Dear Dr. Wakeham:

Since we first submitted to you a proposal on the development of a combustionless cigarette in May, 1960, we have given considerable thought to this idea. During the past 3 years, we have obtained more experience in aerosol formulation and generation, valve design, and tobacco chemistry. Several members of our staff are now even more enthusiastic about the chances of success in developing a combustionless cigarette. Undoubtedly this is an opportune time to introduce such a product to the market.

We have planned a new research program for your consideration. Four copies are attached. The proposed modified program covers two phases: (1) development of a tar-free formulation to be aerosolized to produce simulated cigarette smoke acceptable to smokers and (2) development of a pneumatically actuated metering valve. A third phase consisting of the development of the complete package resembling a regular cigarette would be proposed following the successful conclusion of Phases 1 and 2.

You can authorize us to start work immediately by returning one signed copy of our standard research agreement, two copies of which are attached. We will, of course, be happy to discuss the proposed study with you in detail. We would certainly welcome your visiting Battelle to meet with some of us who would be involved in the research.

Sincerely yours,



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In quadruplicate  
Enc. (6)

Ralph I. Mitchell  
Program Director  
Environmental Mechanics Research

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PROPOSED RESEARCH PROGRAM

on

DEVELOPMENT OF A COMBUSTIONLESS CIGARETTE

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PHILIP MORRIS, INCORPORATED

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Largely because of health worries on the part of smokers, the cigarette market reached a plateau last year after many years of steady growth. For the first time since 1954 the per-capita consumption of cigarettes declined. These statistics suggest the urgent need for a cigarette that will greatly reduce health worries. If, in addition, the fire hazard and possible objections to odor and smoke in public meeting places could be eliminated, the market could be substantially extended. For example, in plants that process flammable materials, employees are generally not permitted to smoke except in specially designated areas. The market potential for a combustionless cigarette is obviously tremendous.

Battelle's concept of a metered aerosol combustionless cigarette was first discussed with Dr. Helmut Wakeham and other members of Philip Morris' research staff in the spring of 1960, and a proposal on the subject was submitted on May 25, 1960. Recently, in a telephone discussion, Dr. Wakeham suggested that a modification of this proposal be resubmitted. The following proposed program outlines Battelle's general thinking on the subject at this time.

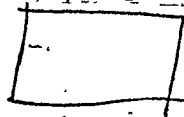
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that Volume would be lost here  
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 introduction -

$$.75 \text{ cm}^2 \times .75 \text{ cm}^3 = .75 \text{ grams}$$

$$\frac{.75}{100} \times 770^2$$



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### Concept of the Final Product

The essential components of the proposed combustionless cigarette are (1) a vial containing the pressurized formulation, (2) a system to permit recharging or replacement of the vial, probably replacement, (3) a metering valve to generate a metered dose of aerosol, (4) a mechanism to actuate the valve by the slight vacuum created by taking a puff, and (5) an outer structure resembling a cigarette to contain these components.

Figure 1 is a sketch of the combustionless cigarette as it is presently visualized.

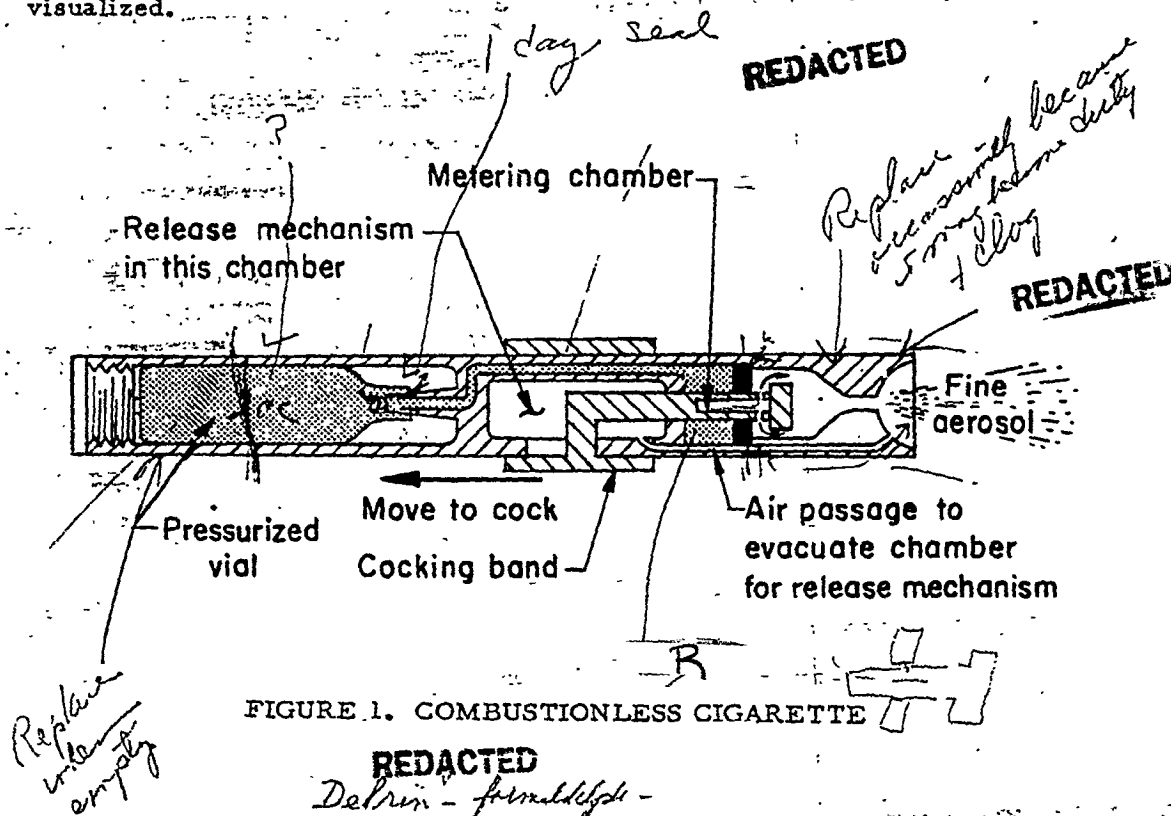


FIGURE 1. COMBUSTIONLESS CIGARETTE

To use this cigarette, the smoker will first cock the valve by depressing a button. He will then draw through the mouthpiece end which will reduce the pressure and automatically trigger the metering valve and discharge an

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accurately metered dose of aerosol into his mouth. By this procedure the release of aerosol will be synchronized with puffing, thereby insuring that the metered dose is taken into the buccal cavity and not wasted.

In order to simulate the flow conditions of a regular cigarette, provision should be made for leakage of a small amount of air into the mouthpiece during the puffing that causes the mechanism to actuate the metering valve. Then, after aerosol is released into the smoker's mouth, he will open his mouth and inhale a large volume of air as he does when smoking a conventional cigarette. In this way the mechanics for smoking the combustionless cigarette will be the same as for smoking a regular cigarette.

#### STATUS OF BATTELLE'S BREATH-ACTUATED AEROSOL VALVE RESEARCH

During the past year, Battelle's Mechanical Energy Systems Group developed for a pharmaceutical company a pneumatically actuated metering valve for administering metered doses of an aerosol medicament for inhalation. The unique feature of the valve is that it automatically actuates when the patient inhales through a mouthpiece and releases the medicament at the proper time for deep penetration into the bronchial tract. A similar valve could be used for the combustionless cigarette. The success of the research for the pharmaceutical company substantially increases the probability of success for the research program proposed to Philip Morris and at the same time decreases the estimated cost of the program.

Preliminary discussions with the pharmaceutical sponsor, who is applying for patents on the valve but who has no commercial interest in tobacco, indicates that he is willing to cooperate with a tobacco company in further development of the valve.

It is estimated that the breath-actuated valve for pharmaceutical aerosols can be manufactured for **REDACTED**. The cost of a smaller valve for the combustionless cigarette may be slightly higher, but it should be possible to use it for a long period of time, somewhat as one would use a cigarette holder.

As Dr. Wakeham is aware, Battelle has had many years' experience in studies of cigarette smoke and pharmaceutical aerosols for inhalation therapy that would contribute to the success of the proposed research.

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## PROBLEMS TO BE SOLVED

In addition to adapting the pharmaceutical metering valve for use in the combustionless cigarette, it will be necessary to formulate a suitable liquid to be aerosolized and to design a holder that will be both functional and attractive.

### Formulation of Liquid to be Aerosolized

The liquid to be aerosolized from the pressurized vial should contain nicotine in such a concentration that each metered dose, possibly 50 mg, will contain the amount of nicotine in a 35-cc puff. On the basis that a cigarette contains 1.0 mg of nicotine and is consumed in 10 puffs, each dose of aerosol should contain 0.1 mg of nicotine.

By a similar calculation the appropriate amounts of additives to create the desired flavor and aroma can be determined. If necessary, a solvent can be included in the formulation to insure that all ingredients are miscible with the propellant. The fluorinated hydrocarbons that are used as propellants are not particularly good solvents, and a small amount of some solvent such as ethyl alcohol may be required to obtain a homogeneous solution. A masking agent for the propellant may also be required. Provision should be made for mixing the proper volume of air with each dose of metered aerosol.

The complete formulation could be contained in a small (maybe 2 cc) vial made of metal or transparent plastic which could be discarded when empty. At 50 mg per puff, a 2-cc vial would provide 40 puffs, or the equivalent of about four cigarettes.

### Holder for Vial and Metering Valve

The final product should resemble a regular cigarette in size, shape, and color. The principal problem will be miniaturizing the breath-actuated metering valve so it can be fitted into the mouthpiece end of the combustionless cigarette. The valve will be a permanent part of the holder which will be a rather simple, inexpensive tube. The inexpensive mouthpiece and orifice through which the formulation is aerosolized could then be discarded at the end of each day.

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There is no doubt that considerable indoctrination, advertising, and promotion programs of various sorts would be required to gain acceptance of such an innovation by the general public. However, a large market that otherwise might be irretrievably lost could probably be retained. One could cite the parallel development in percolator coffee and powdered coffee.

### RESEARCH PROCEDURE

The experimental program will be in two phases: (1) development of the aerosol formulation and evaluation of its acceptability by smokers and (2) miniaturization and adaptation of the breath-actuated metering valve. Following the successful conclusion of these two phases, which would establish the feasibility of the combustionless cigarette, a third phase would be proposed to develop the complete cigarette package.

#### Phase I. Development of Aerosol Formulation and Evaluation of Its Acceptability

Using the physical package now available for administering pharmaceuticals, the ingredients required for an acceptable combustionless cigarette will be selected and formulated. It is expected that the research staff of Philip Morris will provide substantial guidance and advice, and also some of the ingredients for the aerosol formulation. The various formulations considered will be evaluated in Battelle's Sensory Evaluation Laboratory using a panel of smokers and also in Philip Morris' Evaluation Laboratory if they so desire. It is likely that several different formulations, with and without menthol, will be developed to correspond to different brands of cigarettes.

If this evaluation with smokers indicates that the combustionless cigarette is feasible, Phase II will be undertaken.

#### Phase II. Miniaturization and Adaptation of Breath- Actuated Pharmaceutical Metering Valve

Starting with the valve already developed for administering pharmaceutical aerosols, work will be undertaken by Battelle's Mechanical Energy Systems Group to reduce the over-all diameter to that of a cigarette and otherwise

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adapt this valve to the proposed application. An effort will be made to generate aerosol particles in the 1 to 8-micron size range so they can be readily inhaled. Size will play a major role in taste response. It is estimated that this research will require at least 6 months' effort.

#### BATTELLE'S COMPETENCE IN THE FIELDS OF AEROSOLS, CIGARETTE SMOKE, AND VALVE DESIGN

Battelle has conducted research in aerosols for many years, especially pharmaceutical aerosols. Much effort has been spent on the development of nebulizing devices and on studies of the optimum particle size for retention in the respiratory tract. Three years were devoted to studies of the particle size, coagulation, and retention of cigarette smoke. Work on the development of the breath-actuated metering valve during the past year is of special interest to this program. Battelle has a well-equipped aerosol laboratory to carry out formulation studies and a well-staffed machine shop to aid with the design of a metering valve. Members of Battelle's staff are well acquainted with suppliers of components for aerosol packages required for the final design of the proposed combustionless cigarette.

#### REPORTS AND LIAISON

Scheduled conferences will be arranged with Dr. Wakeham, or his designated representative, as the occasion requires. Informal monthly letter reports will be submitted describing the research activities and the progress made. A final summary report, including recommendations for production of combustionless cigarettes, will be prepared at the conclusion of the research.

#### TIME AND COSTS

It is estimated that the proposed research will require 12 months and an appropriation of

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DISCOVERIES AND PATENTS

As explained earlier, special arrangements will be necessary for Philip Morris to share certain rights acquired by the pharmaceutical company that sponsored the earlier work on the metering valve. In recent correspondence with Battelle, they have expressed their willingness to cooperate with a tobacco company on further exploitation of the device. However, they do not think it necessary to spell out detailed licensing or other arrangements at this time, although they are willing to do so if Philip Morris particularly wishes it. Should Philip Morris decide to sponsor the proposed research program, they could designate representatives to discuss the matter with the pharmaceutical company. Battelle will provide the necessary liaison. The cost of any assistance from Battelle's Patent Section in connection with patent matters would be in addition to that estimated for the research program.

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